

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

May 4, 2016

Nicole Listner Associate Regulatory Affairs II Ecolab, Inc. 370 N. Wabasha Street St. Paul, MN 55102

Subject: Notification per PRN 98-10 – To update label language

Product Name: Tsunami 100

EPA Registration Number: 1677-164 Application Date: April 05, 2016

Decision Number: 516824

Dear Ms. Listner:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped "Notification" and will be placed in our records.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you have any questions, you may please contact Emilia Oiguenblik by phone at 703-347-0199, or via email at Oiguenblik.emilia@epa.gov or Julie Chao by phone at 703-308-8735, or via email at Chao.Julie@epa.gov.

Sincerely,

Julie Chao, Product Manager 33 Regulatory Management Branch 1 Antimicrobials Division (7510P)

Office of Pesticide Programs

Tsunami 100

Water Additive for Pathogen* Reduction in (Fruit and Vegetable) Processing Water (and) Controlling the Growth of Spoilage and Decay Causing Non-Public Health Organisms (on Fruit and Vegetable Surfaces)

For Organic Production.

Tsunami 100 may be used as a water additive in (fruit and vegetable) processing water on products labeled as organic in food processing facilities (on both raw agricultural commodities and on fruits and vegetables that will be further processed).

Active Ingredients:

Peroxyacetic acid	15.2%
Hydrogen peroxide	11.2%
Inert Ingredients:	<u>73.6%</u>
Total:	100.0%

KEEP OUT OF REACH OF CHILDREN DANGER

NOTIFICATION

1677-164

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

5/4/2016

(See [back] [side] [other] label for [complete] [additional] [directions for use] [precautionary statements] [and] [first aid])

(Refer to the (MSDS)(SDS) for additional product hazard information)

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CORROSIVE: Causes severe eye damage and skin burns. Harmful or fatal if swallowed. Do not get in eyes, on skin, or on clothing. Wear chemical goggles, rubber gloves, and protective clothing if handling concentrate. Wash thoroughly with soap and water after handling and before eating, drinking, and chewing gum, or using tobacco. Remove any contaminated clothing and wash before re-use.

FIRST AID

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 –20 minutes. Call a poison control center or doctor for treatment advice.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

FOR EMERGENCY MEDICAL INFORMATION CALL TOLL-FREE: 1-800-328-0026

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. See side/back panel for First Aid

PHYSICAL AND CHEMICAL HAZARDS:

Strong oxidizing agent. Corrosive. Do not use in concentrated form. Mix only with water according to label instructions. Never bring concentrate in contact with other sanitizers, cleaners or organic substances.

ENVIRONMENTAL HAZARDS: (containers 5 gallons or greater) This product is toxic to birds, fish, and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

Optional:

Used as directed, *Tsunami 100* reduces 99.9% of the pathogens *Escherichia coli* O157:H7 (ATCC 43895, 35150, 43890)*, *Listeria monocytogenes* (ATCC 49594, 19114, 19116) * and *Salmonella enterica* (ATCC 10721, 6962, 13311).* in fruit and vegetable processing waters. *Tsunami 100* also provides control of spoilage and decay causing non-public health organisms present in processing waters and on the surface of post-harvest, fresh-cut and processed fruits and vegetables.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

FOR PATHOGEN* REDUCTION AND CONTROL IN FRUIT AND VEGETABLE PROCESSING WATERS IN FOOD FACILITIES:

- A. Batch systems with no makeup water added:
 - 1. Ensure that water is mixing in the processing vessel.
 - 2. Add *Tsunami 100* at a rate from 2.5-6.7 fluid ounces per 100 gallons of process water. This will produce about 215-575 ppm total product and about 30-80 ppm peroxyacetic acid. At this use dilution, *Tsunami 100* will provide a 99.9% reduction against the pathogens *Escherichia coli* O157:H7*, *Listeria monocytogenes** and *Salmonella enterica*.*.
 - 3. Measure the residual peroxyacetic acid concentration in the water using a Test Kit (consult Ecolab Representative) and adjust dose as needed. Allow a 1.5 minute mixing time.
- B. Continuous systems with makeup water continuously added:

Initial dose:

- 1. Ensure that water is mixing in the processing vessel and/or piping.
- 2. Add *Tsunami 100* at a rate from 2.5-6.7 fluid ounces per 100 gallons of process water. This will produce about 215-575 ppm total product and about 30-80 ppm peroxyacetic acid. At this use dilution, *Tsunami 100* will provide a 99.9% reduction against the pathogens *Escherichia coli* O157:H7*, *Listeria monocytogenes** and *Salmonella enterica*.*.
- 3. Measure the residual peroxyacetic acid concentration in the water using a Test Kit (consult Ecolab Representative) and adjust dose as needed. Allow a 1.5 minute mixing time.

Continuous Dosing:

Meter *Tsunami 100* at a rate from 2.5-6.7 fluid ounces per 100 gallons of fresh makeup water added to the system. This will produce about 215-575 ppm total product and about 30-80 ppm peroxyacetic acid. Measure the residual peroxyacetic acid concentration in the water using a Test Kit (consult Ecolab Representative) and adjust dose as needed. Allow a 1.5 minute mixing time.

FOR TREATMENT OF FRUIT AND VEGETABLE SURFACES AND PROCESS WATERS IN FOOD FACILITIES:

This product is not intended for control of any public health organisms on fruit and vegetable surfaces. Mix *Tsunami 100* with water either batch-wise or continuously to produce about 36 - 575 ppm total product and about 5 - 80 ppm peroxyacetic acid in use solution. This can be accomplished by initially adding *Tsunami 100* at a rate from 0.42 - 6.7 fluid ounces per 100 gallons of process water. The fruits and vegetables can be sprayed or submerged in the resulting solution for a minimum contact time of 90 seconds, followed by adequate draining. At this use dilution, *Tsunami 100* will control the growth of spoilage and decay causing non-public health organisms, including odor causing organisms, in process waters and on the surface of fruits and vegetables.

Tsunami 100 can be used on the following types of fresh, post harvest and further processed fruits and vegetables:

Vegetables

Root and tuber vegetables: Carrot, potato, radish, rutabaga, sweet potato, yam, sugar beet

- ♦ Leaves of root and tuber vegetables: Turnip greens and sugar beet
- ♦ Bulb vegetables: Onion (dry bulb and green), leek, garlic, shallot
- Leafy vegetables: Lettuce (head and leaf), celery, fennel, endive, escarole, parsley, radicchio, rhubarb, spinach, arugula
- Brassica leafy vegetables: Broccoli, Brussel sprouts, cabbage, cauliflower, mustard greens, mustard spinach
- ◆ Legumes [succulent or dried], bean (green, kidney, lima, mung, navy, pinto, snap, wax), pea (chickpea, lentil, dwarf, garden, English, field, edible pea pod), alfalfa, and soybean
- Fruiting vegetables: Pepper (bell, pimento, hot, sweet), tomato, tomatillo, eggplant
- ♦ Cucurbits: Cucumber, melon (cantaloupe, crenshaw melon, honeydew, honey ball melon, mango melon, muskmelon, pineapple melon, watermelon), summer squash, pumpkins, winter squash Fruits
- Citrus fruits: Sweet and sour orange, lemon, lime, tangelo, tangerine, mandarin, citrus citron, kumquats, grapefruit
- Pome fruits: Apples and pears
- ♦ Stone fruits: Sour and sweet cherry, peach, nectarine, plum, and prune
- Small Fruits and berries: Blackberries, blueberries, red and black raspberries

<u>Sprouts and seeds of</u>: vegetables and fruits that are listed on this label including, root & tuber vegetables, bulb vegetables, leafy vegetables, *Brassica* leafy vegetables, legumes, fruiting vegetables, cucurbits, citrus fruits, pome fruits, stone fruits, small fruits and berries, mustard

<u>Tree nuts</u>: Almond, Brazil, filbert, cashew, pecan, walnut (black & English), macadamia, chestnut <u>Cereal grains</u>: Corn, barley, oats, rice, wheat, triticale, wild rice, sweet corn

<u>Herbs and Spices</u>: Basil, chives, coriander, dill, lemongrass marjoram, sage, savory, tarragon, thyme, ginger root, rosemary, cilantro, oregano, spearmint, mint family

<u>Miscellaneous</u>: Asparagus, avocado, artichoke, banana, cranberry, fig, grape, kiwifruit, mango, mushroom, okra, peanut, persimmon, pineapple, raisins, strawberry, water chestnut, watercress, coffee berry, coffee bean, seaweed

FOR TREATMENT OF SEEDS NOT INTENDED FOR HUMAN OR ANIMAL CONSUMPTION:

Apply to seeds as directed to control seedborne microorganisms that cause plant disease or spoilage and decay of developing seedlings. Only treat seeds of the crops listed on this label. Mix *Tsunami 100* with clean water either batchwise or continuously to no more than 11,500 ppm total product (1750 ppm residual peroxyacetic acid) in use solution. This can be accomplished by adding 20 fluid ounces *Tsunami 100* per 16.4 gallons of water . The volume of treatment solution must be at least two times greater than the volume of seeds to be treated. The seeds must be submerged in the treatment solution and agitated for 30 minutes. Following treatment, remove seeds from treatment solution and dry.

FOR PATHOGEN* REDUCTION AND CONTROL IN (INDUSTRIAL) PROCESSING WATERS IN FOOD FACILITIES:

- A. Batch systems with no makeup water added:
 - 1. Ensure that water is mixing in the processing vessel.
 - 2. Add *Tsunami 100* at a rate from 2.5-6.7 fluid ounces per 100 gallons of process water. This will produce about 215-575 ppm total product and about 30-80 ppm peroxyacetic acid. At this use dilution, *Tsunami 100* will provide a 99.9% reduction against the pathogens *Escherichia coli* O157:H7*, *Listeria monocytogenes** and *Salmonella enterica*.*.
 - 3. Measure the residual peroxyacetic acid concentration in the water using a Test Kit (consult Ecolab Representative) and adjust dose as needed. Allow a 1.5 minute mixing time.
- B. Continuous systems with makeup water continuously added:

Initial dose:

- 1. Ensure that water is mixing in the processing vessel and/or piping.
- 2. Add *Tsunami 100* at a rate from 2.5-6.7 fluid ounces per 100 gallons of process water. This will produce about 215-575 ppm total product and about 30-80 ppm peroxyacetic acid. At this use dilution, *Tsunami 100* will provide a 99.9% reduction against the pathogens *Escherichia coli* O157:H7*, *Listeria monocytogenes** and *Salmonella enterica*.*.
- 3. Measure the residual peroxyacetic acid concentration in the water using a Test Kit (consult Ecolab Representative) and adjust dose as needed. Allow a 1.5 minute mixing time.

Continuous Dosing:

Meter *Tsunami 100* at a rate from 2.5-6.7 fluid ounces per 100 gallons of fresh makeup water added to the system. This will produce about 215-575 ppm total product and about 30-80 ppm peroxyacetic acid. Measure the residual peroxyacetic acid concentration in the water using a Test Kit (consult Ecolab Representative) and adjust dose as needed. Allow a 1.5 minute mixing time.

FOR TREATMENT OF (INDUSTRIAL) PROCESS WATERS IN FOOD FACILITIES:

This product is not intended for control of any public health organisms. Mix *Tsunami 100* with water either batch-wise or continuously to produce about 36 - 575 ppm total product and about 5 - 80 ppm peroxyacetic acid in use solution. This can be accomplished by initially adding *Tsunami 100* at a rate from 0.42 - 6.7 fluid ounces per 100 gallons of process water. At this use dilution, *Tsunami 100* will control the growth of spoilage and decay causing non-public health organisms, including odor causing organisms, in process waters.

SANITIZATION:

Tsunami 100 acid sanitizer is recommended for use on pre-cleaned surfaces such as equipment, pipelines, tanks, vats, fillers, evaporators, pasteurizers and aseptic equipment dairies, breweries, wineries, beverage and food processing plants. This product is effective as a sanitizer when solution is prepared in water of up to 500 ppm hardness.

SANITIZING FOOD CONTACT SURFACES

Prior to use of this product, remove gross soil particles from surfaces, thoroughly clean surfaces, and follow with a potable water rinse. Sanitize clean surfaces with a concentration of 0.10-0.18% v/v (1000 to 1800 ppm v/v or 1 to 1.8 ounces per 8 gallons of water) at room temperature. Use immersion, coarse spray or circulation techniques as appropriate to sanitize the surfaces. All surfaces must be exposed to the sanitizing solution for a period of not less than one minute unless otherwise specified by governing sanitary code. Allow surfaces to drain thoroughly and air dry. Do not rinse. This product when used per label directions is effective against Staphylococcus aureus (ATCC 6538) and Escherichia coli (ATCC 11229).

CLEANING HARD SURFACE:

CLEANING HARD SURFACE FOOD PROCESSING EQUIPMENT- NO RINSE

For hard surface cleaning applications, remove gross soil particles from surfaces, then thoroughly clean surfaces with a concentration of 0.10 - 0.18% v/v (1000 to 1800 ppm v/v or 1 to 1.8 ounces per 8 gallons of water). Use immersion, coarse spray or circulation techniques as appropriate to clean surfaces. Allow surfaces to drain thoroughly. No rinse necessary.

FINAL BOTTLE AND CLOSURE CLEANING RINSE

Tsunami 100 may be used as a final cleaning rinse for returnable and non-returnable bottles (e.g. glass or PET) and closures not requiring a final food contact surface sanitizing rinse when used at a concentration of 0.10 - 0.18% v/v (1000 to 1800 ppm v/v or 1 to 1.8 ounces per 8 gallons of water). Drain thoroughly. No rinse necessary.

CLEANING HARD SURFACE PROCESSING EQUIPMENT—RINSE FOR FOOD CONTACT SURFACES For hard surface cleaning applications, remove gross soil particles from surfaces, then thoroughly clean surfaces with 2 to 3 ounces product per 3 gallons of water (0.5% to 0.8% v/v). All treated hard non-porous food contact surfaces must be rinsed thoroughly with a potable water rinse.

FLOODING AND PRODUCED WATER IN FOOD FACILITIES:

For Water Flooding operations, add Tsunami 100 initially at 3.75 fluid ounces per 1000 gallons of water (5ppm peroxyacetic acid by weight) to 75.5 fluid ounces per 1000 gallons of water (100 ppm peroxyacetic acid by weight) and repeat until control is achieved. Subsequent treatment may be continued on a weekly basis or as required.

NOTE: This product in its use solutions is compatible with stainless steel and aluminum surfaces. If product is intended to be used on any other surface, it is recommended that you apply product to a smaller test area to determine compatibility before proceeding with its use.

STORAGE & DISPOSAL:

DO NOT CONTAMINATE WATER, FOOD OR FEED BY STORAGE OR DISPOSAL

PESTICIDE STORAGE: Product must be kept cool and in a vented container to avoid any explosion hazard.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER HANDLING AND DISPOSAL:

(For containers 5 gallons or less.) Non-refillable container. Do not reuse or refill this container. Triple rinse as follows: Fill container ¼ full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times. Then offer for recycling or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by incineration.

(For containers >5-55 gallons.) Non-refillable container. Do not reuse or refill this container. Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat procedure two more times. Then offer for recycling or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by incineration.

(300 gallon tote) Verify that the tote is empty. Do not rinse or clean. Seal tote and contact Ecolab for return.

FOR INSTITUTIONAL USE

STRONG OXIDIZING AGENT

EPA Reg. No. 1677-164

EPA Est.: 1677-MN-1 (P), 60156-IL-1 (SI), 1677-CA-2 (R), 1677-TX-1 (D), 1677-IL-2 (J), 1677-GA-1 (M),

1677-WV-1 (V)

Superscript refers to first letter of date code

(Made in United States of America) (Made in USA)

Net Contents: 4 U.S. Gallons (15.1 liters) 50 U.S. Gallons (189 liters) 300 U.S. Gals. (1134 liters)

Manufactured by: Ecolab Inc., Food & Beverage Division 370 Wabasha Street N., St. Paul, MN 55102



Antimicrobial

SECONDARY CONTAINER LABEL

(Note to reviewer: This secondary/use dilution container label will be used only when the product is diluted with no more than 20 oz. product per 16.4 gallon of water, 0.95% v/v.—Use dilution is to be prepared by end user. This secondary/use dilution label will only be used by the end user and will not be sold or distributed.)

When this product is diluted in accordance with the directions on this label, the dilution container must bear the following statements:

	Tsu	nami 100	
Concentrate Ingredient S	Statement		
Active Ingredients:			
Peroxyacetic aci	d	15.2%	
Hydrogen peroxi	de	11.2%	
Inert Ingredients:		<u>73.6%</u>	
Total:		100.0%	
The product in this container must be diluted at the use rate with no more than 20 oz.product per 16.4 gallon of water, or 0.95% v/v, as directed on the concentrate product label.			
Dilution:	oz product per	gallons of water	

KEEP OUT OF REACH OF CHILDREN

USE DILUTION PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Caution. Causes moderate eye irritation. Harmful in swallowed. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

(FIRST AID

If in Eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.

If Swallowed: Call a poison control center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.)

Follow the directions for use listed on the concentrate label when applying this product.

Use solution prepared by end user. Not for sale or distribution (Do Not Drink)

EPA Reg. No. 1677-164